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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,491	07/07/2003	Bryan Loomas	BRONNE00600	8889

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LEVINE BAGADE HAN LLP
2483 EAST BAYSHORE ROAD, SUITE 100
PALO ALTO, CA 94303

EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/615,491

Applicant(s)

LOOMAS ET AL.

Examiner

Peter J. Vrettakos

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 24-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The action is non-final.

Note: independent claim 1 is too brief and broad, and simply claims creating what already occurs in nature: creating a connection (bronchial airways) between an extrapleural airway (trachea) and the lungs. The claim also presupposes that it is appropriate to delineate a bronchial airway as being extrapleural versus intrapleural. A Google search, EAST search and Derwent search of the phrase "extrapleural airway" yields nothing except the Applicant's patent work. A Google Scholar search yields nothing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant merely claims what already occurs in nature: creating a connection between the lungs and the trachea (i.e. bronchial airways). Furthermore, the Applicant relies upon a vague definition of what constitutes an extra versus inter pleural airway to obviate rejections. Although the trachea is clearly an extrapleural airway at what point does a bronchial airway (which progresses into increasingly smaller airways as it traverses into the lung) become an intrapleural airway? One cannot say that all bronchi are extrapleural or intrapleural because a

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bronchus can be both. Even more, due to anatomical differences amongst a population can that universal delineation between intra and extrapleural airways even be determined? At this point the Applicant is requiring the Office to provide arguments that ignore this inherent ambiguity involved in categorizing intra versus extrapleural airways, which will lead to prolonged and burdensome prosecution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al. (6,692,494).

Cooper discloses creating connections between an **airway** (an “extrapleural airway” such as the trachea is certainly an airway) and lung tissue as disclosed in col. 9:29-32. Cooper discloses creating connections within the lungs as depicted in figure 1d. The Applicant is now attempting to claim creating connections across the pleura of the lungs in the upper/middle lobe as seen in Application figure 11b (element 200D). Considering the similarities in the two figures, the Office asserts that it would have been obvious to one of ordinary skill in the art to modify Cooper by creating channels not only within the lung, but also across the lung into the trachea, both procedures for improving

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gas flow in patients with compromised pulmonary function. Further, Cooper discloses placing collateral channels in the bronchi in col. 4:22-25, whereas the Applicant argues that an extrapleural airway can be a mainstem bronchus (remarks dated 4-5-06). The Office asserts that a mainstem bronchus is a bronchi and that the bronchi disclosure makes obvious fluidly connected an extrapleural airway and the lung if the position of the bronchi channel is near the point of entry of the lung. Moreover, Cooper discloses making a collateral channel in the upper/middle lobe (col. 4:26-27), which is clearly that seen in the instant Application figure 11b (element 200D). Another issue is the determination of when an airway is considered extrapleural versus intrapleural, already elaborated above. The motivation to create a “transpleural airway” is to simply build upon what is already disclosed by Cooper (to make a collateral channel in the bronchi) as well as to make a collateral channel between an **airway** and lung tissue (col. 9:29-32)).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keast et al. (6,749,606).

Keast discloses creating connections between an **airway** (an “extrapleural airway” such as the trachea is certainly an airway) and lung tissue as disclosed in col. 8:61-63. Keast discloses creating connections within the lungs as depicted in figure 1d. The Applicant is now attempting to claim creating connections across the pleura of the lungs in the upper/middle lobe as seen in Application figure 11b (element 200D). The Office asserts that it would have been obvious to one of ordinary skill in the art to modify Keast by creating channels not only within the lung, but also across the lung into the

trachea, both procedures for improving gas flow in patients with compromised pulmonary function. Another issue is the determination of when an airway is considered extrapleural versus intrapleural, already elaborated above. The motivation to create a "transpleural airway" is to simply build upon what is already disclosed by Keast (to make a collateral channel in the bronchi) as well as to make a collateral channel between an **airway** and lung tissue (col. 8:61-63)).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laufer et al. (6,629,951).

Laufer discloses creating connections within the lungs as depicted in figure 1d. Laufer discloses creating connections between an **airway** (an "extrapleural airway" such as the trachea is certainly an airway) and lung tissue as disclosed in col. 9:30-32. The Applicant is now attempting to claim creating connections across the pleura of the lungs in the upper/middle lobe as seen in Application figure 11b (element 200D). Considering the similarities in the two figures, the Office asserts that it would have been obvious to one of ordinary skill in the art to modify Cooper by creating channels not only within the lung, but also across the lung into the trachea, both procedures for improving gas flow in patients with compromised pulmonary function. Further, Cooper discloses placing collateral channels in the bronchi in col. 4:25-28, whereas the Applicant argues that an extrapleural airway can be a mainstem bronchus (remarks dated 4-5-06). The Office asserts that a mainstem bronchus is a bronchi and that the bronchi disclosure makes obvious fluidly connected an extrapleural airway and the lung if the position of the bronchi channel is near the point of entry of the lung. Moreover, Cooper discloses

making a collateral channel in the upper/middle lobe (col. 4:26-27), which is clearly that seen in the instant Application figure 11b (element 200D). Another issue is the determination of when an airway is considered extrapleural versus intrapleural, already elaborated above. The motivation to create a "transpleural airway" is to simply build upon what is already disclosed by Laufer (to make a collateral channel in the bronchi) as well as to make a collateral channel between an **airway** and lung tissue (col. 9:30-32)).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Pete Vrettakos
June 26, 2006



ROY D. GIBSON
PRIMARY EXAMINER